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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/762,476 | 09/27/2001 | Michael Mendez | 40977 | 5080 |

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Steven B. Kelber, Esq.
Piper Rudnick, LLP
1200 19th Street N.W.
Washington, DC 20036

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| EXAMINER |
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AKHAVAN, RAMIN

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| ART UNIT | PAPER NUMBER |
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1636

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DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

File

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 09/762,476 | Applicant(s) MENDEZ ET AL. | |
| | Examiner Ramin (Ray) Akhavan | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-47 is/are pending in the application.
4a) Of the above claim(s) 14-19, 23-26 and 33-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 20-22 and 27-31 is/are rejected.
- 7) ☒ Claim(s) 7-13 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This action is in response to amendments filed on July 25, 2003 in which claim 1-4, 6 and 20 were amended and claim 5 was canceled. Any objections or rejections not repeated herein have been withdrawn. Claims 1-4, 6-13, 20-22 and 27-32 are examined in this action.

Response to Arguments

Applicant's arguments, see Remarks filed 07/25/2003, with respect to rejections pursuant to 35 U.S.C. §§ 102 and 103 have been fully considered and are persuasive. The rejections have been withdrawn.

Claim Objections

Claims 7-13 and 32 are objected to as being dependent from a rejected claim.

New Grounds for Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1. Claims 1-4, 6, 20, 27-28 and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Hodges et al. (US 5,744,336)(hereinafter '336).**

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The claims are drawn to a vector system and cells comprising said vector system that has a first and second selectable marker, cyclization element, 5' and 3' sequences homologous to a target polynucleotide with an origin of replication.

The system may further comprise a rare restriction site, a polylinker, two cyclization elements comprising LOX sites, two selectable marker genes, a target sequence. The system can be contained in a eukaryotic cell or bacterial cell.

The '336 patent teaches a vector construct system with a left and right arm. (e.g. Fig. 1A). Furthermore, the vector construct system comprises a target sequence, a homologous region to a target sequence, two recombination target sequences (i.e. cyclization element), a polylinker region and a selectable marker gene (e.g. Fig. 1A), as well as an origin of replication (e.g. Fig. 1B). In addition the '336 patent teaches that the vector system can comprise a second selectable marker gene (e.g. Fig. 8), and that the vector construct can comprise a unique (i.e. rare) restriction site. (e.g. col. 2, ll. 39-42). Further, '336 teaches that the vector system comprises a polylinker. (e.g. col. 6, ¶ bridging to col. 7). The '336 also teaches that the recombination (or cyclization) elements on the vector can be LOX sites. (e.g. Fig. 9 D-F). In addition '336 teaches that the vector system can comprise a target sequence. (Figs. 4A-B and 5; col. 6, ll. 33-55). Moreover, '336 teaches that the targeted host cells can be eukaryotic (e.g. col. 8, ll. 12-15; *see also*, col. 29, l. 1; col. 30, l. 1), as well as that bacterial strains can contain the vector system (e.g. modifying the Ti or Ri system in bacteria to contain the vector system; col. 3, ll. 25-35; col. 29, ll. 49-52). In light of the foregoing teachings, the '336 patent anticipates the rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claim 21, 22, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 5,744,336)(hereinafter '336).

The claims are drawn to yeast cells, more specifically *S. cerevisiae*, where said yeast cell comprises the vector system of base claim 1. Although the '336 patent does not explicitly state that *S. cerevisiae* can comprise the vector system taught, it does indicate that different site specific recombinase systems can be used, such as Cre/Lox of phage, FLP/FRT of yeast and Pin recombinase of *E. coli*. (e.g. col. 5, ll. 40-45). It would reasonably follow that if the recited cyclization elements are known to be derived from and effective in yeast or bacteria, then it would be obvious to one of ordinary skill in the art to use the vector system taught to transform

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yeast cells, the most well known species of which is *S. cerevisiae*. Indeed ‘Yeast’ commonly refers to *S. cerevisiae* reflecting its widespread use and pre-eminence as a model organism. (*see generally*, Walmsley and Keenan, *The Eukaryote Alternative: advantages of using yeasts in place of bacteria in microbial biosensor development*. Under Section Two, available at URL: <gentronix.co.uk/keypapers/WalmsleyBBEreview.pdf>) (last visited 12/11/03) (noting that ‘Yeast’ usually refers to *S. cerevisiae*, reflecting its widespread use and pre-eminence as a model organism).

A recombination-based system that contains elements such as LOX or FRT would intrinsically be capable of homologous recombination in cells that contain the site-specific cognate recombinase, e.g. Cre in *E. coli* or FLP in *S. cerevisiae*. The ‘336 patent teaches that the vector system can contain various, well-known recombinase systems (i.e. cyclization elements)(e.g. col. 5, ll. 40-45; Figs. 4A-B, 9A-9F), stating that, “In these systems a recombinase (Cre or FLP) will interact specifically with its respective site-specific recombination sequence (lox or FRT) to invert or excise the intervening sequences.” (col. 5, ll. 48-51).

It would have been obvious to use the vector system taught to transform different eukaryotic organisms such as yeast, more specifically *S. cerevisiae* that contain the respective site-specific recombination sequence necessary for a recombination event. The ordinary skilled artisan, seeking to expand the range of organisms that could be transformed with the disclosed vector system, would have been motivated to transform yeast cells (*S. cerevisiae*) with the vector constructs taught. Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of applicant’s invention, it must be considered that said skilled artisan would

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have had a reasonable expectation of success in transforming yeast (i.e. *S. cerevisiae*) with the vector system that the '336 patent teaches.

Conclusion

Claims 1-4, 6-9, 20-22, 27-28 and 31 are rejected under new grounds. Claims 7-13 and 32 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.